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SEP 13 2011

Appendix G - 510(k) Summary for the Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platforms

I. General Information

Sponsor/ 510(k) Owner	**Sponsor** Alma Lasers, Inc.		
Address and Establishment Registration #	485 Half Day Rd. Suite No. 100 Buffalo Grove, IL 60089, USA FDA Registration #: 3004167969		
Contact Person:	Tatiana Epstein VP QA&RA Alma Lasers, Inc.	Telephone: Facsimile: Email:	(224) 377-2011 (224) 377-2050 Tatiana.epstein@almalasers.com

Summary Preparation Date: September 13, 2011

II. Names

Device Names: Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platforms

Primary Classification Names:	Laser Powered Surgical Instruments (and accessories)
Regulation Number:	21 CFR 878.4810
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class:	Class II
Product Code:	GEX

III. Predicate Devices

- Modified Alma Lasers Family of Soprano Multi-Application Platforms [Soprano XL™, Soprano XLi™] (K102716)
- Alma Lasers Soprano XL Multi-Application Platform (K083848)

IV. Product Description

The Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platforms, and the delivery accessories that are used with it, is comprised of the following main components:

- A module housing with:
  - Module trigger switch (must be pressed at the same time the Soprano system footswitch is depressed to deliver laser energy to the treatment site);
  - Light guide
    - TEC-cooled to provide contact skin cooling
  - Light guide retainer
- Umbilical cable and connector that attaches the Diode Laser Module to the Soprano system console and includes the electrical and cooling connections to the Soprano system.

V. Indications for Use

The Alma Lasers Family of Soprano XL Multi-Application Platforms is intended for use in dermatologic and general surgical procedures.

The Alma Lasers Modified Diode Laser Module (used with the Alma Lasers Family of Soprano XL Multi-Application Platforms):

- The HR Mode is intended for hair removal, permanent hair reduction.
- The SHR Mode is intended for hair removal, permanent hair reduction.
- The LaserBlanche Mode is intended for the treatment of benign vascular and pigmented lesions.

The Alma Lasers Family of Soprano XL Multi-Application Platforms is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

VI. Rationale for Substantial Equivalence

The Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platforms shares the same indications for use, device operation, technical and functional capabilities, and therefore is substantially equivalent to the predicate Modified Alma Lasers Family of Soprano Multi-Application Platforms [Soprano XL™, Soprano XLi™] (K102716) and the Alma Lasers Soprano XL Multi-Application Platform (K083848).

Parameter	**K11___** Alma Lasers Modified Diode Laser Module with SHR Treatment Mode used with the Soprano XL Multi-Application Platforms			**K102716** Modified Alma Lasers Family of Soprano Multi-Application Platforms [Soprano XL™, Soprano XLi™]		**K083848** Alma Lasers Soprano XL Multi-Application Platform
Diode Module Mode	SHR Mode	HR Mode	LB Mode	HR Mode	LB Mode	HR Mode
Laser Wavelength	810 nm (nominal)			810 nm (nominal)		810 nm (nominal)
Indications for Use	Intended for hair removal, permanent hair reduction		Intended for treatment of benign vascular and pigmented lesions	Intended for hair removal, permanent hair reduction	Intended for treatment of benign vascular and pigmented lesions	Intended for hair removal, permanent hair reduction
Soprano System Indications for Use	• Intended for use in dermatologic and general surgical procedures • Intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.					
Spot Size	1.2 cm^2			1.2 cm^2		1.2 cm^2
Fluence (Energy Density)	≤ 10 J/cm^2	≤ 120 J/cm^2	≤ 80 J/cm^2	≤ 120 J/cm^2	≤ 80 J/cm^2	≤ 120 J/cm^2
Rep Rate	≤ 10 Hz	≤ 3 Hz		≤ 3 Hz		≤ 3 Hz
Pulse Duration	≤ 20 ms	5-200 ms		5-200 ms		5-200 ms
Compatible Laser Syst.	Used with Family of Soprano XL Multi-Application Platforms			Family of Soprano XL Multi-Application Platforms		Soprano XL System

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platforms is substantially equivalent to the predicate Modified Alma Lasers Family of Soprano Multi-Application Platforms [Soprano XL™, Soprano XLi™] (K102716) and the Alma Lasers Soprano XL Multi-Application Platform (K083848).

In addition, published peer-reviewed medical literature provided device validation information demonstrating that the changes do not raise new questions of safety or effectiveness.

The supporting published information reported on clinical studies in 2,879 patients demonstrating the safety and effectiveness/performance of the 810 nm Diode Laser Module handpiece and the SHR Treatment Mode (used with the Soprano system console) for hair removal and permanent hair reduction.

These studies reported on the safety and effectiveness/performance immediately following treatment and at 1, 6, and 18 months following treatment with the 810 nm Diode Laser Module handpiece and the SHR treatment Mode (used with the Soprano system console) using the low fluence, high repetition rate, multiple-pass treatment regimen.

VIII. Conclusion

The Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platforms was found to be substantially equivalent to the predicate devices.

The Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platforms shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Alma Lasers, Inc.
% A. Worden Consulting
Ms. Anne Worden
485 Half Day Road, Suite 100
Buffalo Grove, Illinois 60089

SEP 13 2011

Re: K112031
Trade/Device Name: Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platform
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 13, 2011
Received: July 15, 2011

Dear Ms. Worden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K112031

Device Name: **Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with the Family of Soprano XL Multi-Application Platforms**

Indications for Use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112031